NOTICE OF INTENT

Department of Environmental Quality
Office of the Secretary
Legal Affairs Division

Compatibility and Health and Safety Requirements (LAC 33:XV.102, 322, 421, 442, 703, 706, 723, 728, 736, 737, 741, 742, 743, 755, 757, 763, and 804) (RP041ft)

Under the authority of the Environmental Quality Act, R.S. 30:2001 et seq., and in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq., the secretary gives notice that rulemaking procedures have been initiated to amend the Radiation Protection regulations, LAC 33:XV.102, 322, 421, 442, 703, 706, 723, 728, 736, 737, 741, 742, 743, 755, 757, 763, and 804 (Log #RP041ft).

This proposed rule is identical to federal regulations found in 10 CFR Parts 20, 31, 35, and 39, which are applicable in Louisiana. For more information regarding the federal requirement, contact the Regulation Development Section at (225) 219-3550 or Box 4302, Baton Rouge, LA 70821-4302. No fiscal or economic impact will result from the proposed rule; therefore, the rule will be promulgated in accordance with R.S. 49:953(F)(3) and (4).

Louisiana's radiation regulations are being updated in order to maintain equivalency with NRC regulations for purposes of compatibility and health and safety significance. These changes are required under the Agreement State Program. Agreement states must periodically review and update their state regulations in order to remain current with federal regulations. In addition to the compatibility issues, a typographical error is being corrected in LAC 33:XV.804. The basis and rationale for this rule are to preserve compatibility of Louisiana's radiation regulations with equivalent NRC regulations.

This proposed rule meets an exception listed in R.S. 30:2019(D)(2) and R.S. 49:953(G)(3); therefore, no report regarding environmental/health benefits and social/economic costs is required. This proposed rule has no known impact on family formation, stability, and autonomy as described in R.S. 49:972.

A public hearing will be held on April 25, 2006, at 1:30 p.m. in the Galvez Building, Oliver Pollock Conference Room, 602 N. Fifth Street, Baton Rouge, LA 70802. Interested persons are invited to attend and submit oral comments on the proposed amendments. Should individuals with a disability need an accommodation in order to participate, contact Judith A. Schuerman, Ph.D., at the address given below or at (225) 219-3550. Free parking is available in the Galvez Garage when the parking ticket is validated by department personnel at the hearing.

All interested persons are invited to submit written comments on the proposed regulation. Persons commenting should reference this proposed regulation by RP041ft. Such comments must be received no later than April 25, 2006, at 4:30 p.m., and should be sent to Judith A. Schuerman, Ph.D., Office of the Secretary, Legal Affairs Division, Box 4302, Baton Rouge, LA

70821-4302 or to FAX (225) 219-3582 or by e-mail to judith.schuerman@la.gov. The comment period for this rule ends on the same date as the public hearing. Copies of this proposed regulation can be purchased by contacting the DEQ Public Records Center at (225) 219-3168. Check or money order is required in advance for each copy of RP041ft. This regulation is available on the Internet at www.deq.louisiana.gov under Rules and Regulations.

This proposed regulation is available for inspection at the following DEQ office locations from 8 a.m. until 4:30 p.m.: 602 N. Fifth Street, Baton Rouge, LA 70802; 1823 Highway 546, West Monroe, LA 71292; State Office Building, 1525 Fairfield Avenue, Shreveport, LA 71101; 1301 Gadwall Street, Lake Charles, LA 70615; 111 New Center Drive, Lafayette, LA 70508; 110 Barataria Street, Lockport, LA 70374; 645 N. Lotus Drive, Suite C, Mandeville, LA 70471.

Herman Robinson, CPM Executive Counsel

Title 33 ENVIRONMENTAL QUALITY Part XV. Radiation Protection

Chapter 1. General Provisions

§102. Definitions and Abbreviations

As used in these regulations, these terms have the definitions set forth below. Additional definitions used only in a certain chapter may be found in that chapter.

* * *

Radiation Safety Officer—one who has the knowledge and responsibility to apply appropriate radiation protection principles and regulations to control exposure to individuals and the environment. A radiation safety officer shall be identified on:

- 1. <u>a specific medical use license issued by the agreement state or Nuclear Regulatory Commission; or</u>
- 2. <u>a medical use permit issued by a Nuclear Regulatory Commission master</u> material licensee.

* * *

Sealed Source—any container of radioactive material that has been encased in a capsule constructed in such a manner as to prevent leakage orthe escape of any radioactive material.

* * *

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), LR 19:1421 (November 1993), LR 20:650 (June 1994), LR 22:967 (October 1996), LR 24:2089 (November 1998), repromulgated LR 24:2242 (December 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2563 (November 2000), LR 26:2767 (December 2000), LR 30:1171, 1188 (June 2004), amended by the Office of Environmental Assessment, LR 31:44 (January 2005), LR 31:1064 (May 2005), amended by the Office of the Secretary, Legal Affairs Division, LR 32:**.

Chapter 3. Licensing of Radioactive Material

Subchapter C. General Licenses

§322. General Licenses: Radioactive Material Other Than Source Material

A. – D.3.c.ii. ...

d. maintain records showing compliance with the requirements of <u>Subparagraphs LAC 33:XV.322.</u>D.3.b and c of this Section. The records shall show the results of

tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation of the radioactive material, its shielding, or containment. Records of tests for leakage of radioactive material required by <u>Subparagraph LAC 33:XV.322.D.3.b</u> of this <u>Section</u> shall be maintained until the sealed source is transferred or disposed. Records of tests of the on-off mechanism and indicator required by <u>Subparagraph LAC 33:XV.322.D.3.b</u> of this <u>Section</u> shall be maintained for one year after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed. Records required by <u>Subparagraph LAC 33:XV.322.D.3.c</u> of this <u>Section</u> shall be maintained for a period of threetwo years from the date of the recorded event or until the device is transferred or disposed;

e. – g. ...

h. transfer the device to another general licensee only:

i. where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this regulation and any safety documents identified in the label on the device and, within 30 days of the transfer, report to the Office of Environmental Compliance, Emergency and Radiological Services Division, the manufacturer's name and the model number of the device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the department and the transferee; or

ii. where the device is held in storage <u>by an intermediate</u> <u>person</u> in the original shipping container at its intended location of use prior to initial use by a general licensee;

D.3.i. – J.4. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2567 (November 2000), LR 27:1226 (August 2001), LR 30:1663 (August 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2524 (October 2005), LR 32:**.

Chapter 4. Standards for Protection against Radiation

Subchapter B. Radiation Protection Programs

§421. Radiation Dose Limits for Individual Members of the Public

A. - A.3. ...

B. If the licensee or registrant permits members of the public to have access to <u>controlledrestricted</u> areas, the radiation dose limits for members of the public continue to apply to those individuals.

C. – E. ...

F. Each licensee or registrant shall conduct operations so that, notwithstanding Paragraph A.1 of this Section, a licensee or registrant may permit a visitor to an individual who cannot be released, under LAC 33:XV.725, to receive a radiation dose greater than 0.1 rem (1 mSv) if:

- 1. the radiation dose received does not exceed 0.5 rem (5 mSv); and
- <u>2.</u> <u>the authorized user</u>, as defined in LAC 33:XV.102, has determined before the visit that it is appropriate.

³Retrofit shall not be required for locations within facilities where only radiation machines existed prior to January 1, 1994, and met the previous requirements of 5 mSv (0.5 rem) in a year.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:1421 (November 1993), LR 22:970 (October 1996), LR 24:2095 (November 1998), repromulgated LR 24:2243 (December 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2576 (November 2000), amended by the Office of Environmental Assessment, LR 31:48 (January 2005), amended by the Office of the Secretary, Legal Affairs Division, LR 32:**.

Subchapter E. Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas

§442. Use of Individual Respiratory Protection Equipment

A. If the licensee or registrant <u>assigns or permits the uses of respiratory protection</u> equipment to limit intakes in accordance with LAC 33:XV.441:

 $1. - 3. \dots$

a. air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures doses;

b. ...

c. tests of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use;

d. - e. ...

f. written procedures regarding: selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and recordkeeping; and

- i. monitoring, including air sampling and bioassays;
- ii. supervision and training of respirator users;
- iii. fit testing;
- iv. respirator selection;
- v. breathing air quality;
- vi. inventory and control;
- vii. storage, issuance, maintenance, repair, testing, and quality

assurance of respiratory protection equipment;

viii. recordkeeping; and

ix. limitations on periods of respirator use and relief from

respirator use;

g. determination by a physician prior to <u>the initial fitting of a</u> respirators, <u>prior to the first field use of a non-face sealing respirator</u>, and at least every 12 months thereafter, or periodically at a frequency determined by a physician, that the individual

user is physically ablemedically fit to use the respiratory protection equipment;

4. – 4.a. ...

- b. the routine, nonroutine, and emergency use of respirators; and
- c. ...
- <u>5d.</u> the <u>licensee or registrant shall make</u> availab<u>le</u>ility of sufficient standby rescue persons to assist all respirator users and to provide effective emergency rescue if needed; and <u>shall</u>
 - e. providesion for the availability of standby rescue persons who:
- $\underline{a}_{\underline{i}}$. are required to be present in situations whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself;
- \underline{bii} . must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards; and
- <u>ciii</u>. shall observe or otherwise maintain continuous communication with the workers (by visual, voice, signal line, telephone, radio, or other suitable means) and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress;
- <u>65</u>. the licensee or registrant shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief; and
- <u>76.</u> the licensee or registrant shall use respiratory protection equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities, such as adequate skin protection, when needed.

B. - D. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:1421 (November 1993), LR 22:972 (October 1996), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2577 (November 2000), LR 29:1469 (August 2003), LR 30:1666 (August 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2529 (October 2005), LR 32:**.

Chapter 7. Use of Radionuclides in the Healing Arts

§703. License Amendments and Provisions for Research Involving Human Subjects $A.-A.6.\ldots$

- B. A licensee may conduct research involving human subjects using radioactive material, provided that the research is conducted, funded, supported, or regulated by a federal agency that has implemented the Federal Policy for the Protection of Human Subjects. The licensee shall, before conducting such research:
 - <u>1.</u> <u>obtain review and approval of the research from an *Institutional Review*</u>

Board, as defined and described in the Federal Policy; and

<u>2.</u> <u>obtain *informed consent*, as defined and described in the Federal Policy, from the human research subject.</u>

C.-D. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), LR 24:2101 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2587 (November 2000), LR 30:1173 (June 2004), amended by the Office of Environmental Assessment, LR 31:1061 (May 2005), amended by the Office of the Secretary, Legal Affairs Division, LR 32:**.

§706. Radiation Safety Officer

A. A licensee shall appoint a radiation safety officer, who agrees, in writing, to be responsible for implementing the radiation safety program. The licensee, through the radiation safety officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

B. – B.4. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2588 (November 2000), amended by the Office of the Secretary, Legal Affairs Division, LR 32:**.

§723. <u>Vial and Vial Shield Labels</u>

A. A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation. Each vial that contains a radiopharmaceutical must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of the Secretary, Legal Affairs Division, LR 32:**.

§728. Decay-in-Storage

A. A licensee shall hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash and is exempt from the requirements of LAC 33:XV.460 of these regulations if the licensee:

1. ...

2. monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 27:1238 (August 2001), LR 30:1177 (June 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 32:**.

§736. Safety Instruction

A. – B.4. ...

5. notification of the radiation safety officer, or <u>his or her designee</u>, and an authorized user, in the case of the patient's or human research subject's death or medical emergency; and

B.6. - C. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2105 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2589 (November 2000), LR 30:1178 (June 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 32:**.

§737. Safety Precautions

A. – A.7. ...

B. A licensee shall notify the radiation safety officer, or <u>his or her designee</u>, <u>and anthe</u> authorized user immediately if the patient or human research subject dies or has a medical emergency.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2105 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2589 (November 2000), LR 30:1178 (June 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2533 (October 2005), LR 32:**

§741. Use of Sources for Brachytherapy

A. - A.5. ...

B. A licensee shall use only <u>brachytherapyradioactive</u> sources for therapeutic medical uses:

 $1. - 2. \dots$

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:1178 (June 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 32:**.

§742. Safety Instructions

A. – B.4.b. ...

5. procedures for notification of the radiation safety officer, or <u>his or her</u> <u>designee</u>, <u>and an</u> authorized user if the patient or human research subject dies or has a medical emergency; and

B.6. – C. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2105 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:1179 (June 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 32:**.

§743. Safety Precautions

A. – B.2. ...

C. A licensee shall notify the radiation safety officer, or <u>his or her designee</u>, and an authorized user immediately if the patient or human research subject dies or has a medical emergency.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2105 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:1179 (June 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 32:**.

§755. Dosimetry Equipment and Therapy-Related Computer Systems

 $A. - A.1 \dots$

2. The system shall have been calibrated within the previous four 4 years; 18 to 30 months after that calibration, the system shall have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The intercomparison meeting shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine. The results of the intercomparison meeting shallmust have indicated that the calibration factor of the licensee's system had not changed by

more than 2 percent. The licensee shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.

B. – D.5. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:1181 (June 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 32:**.

§757. Periodic Spot-Checks

A. – A.2. ...

a. timer <u>accuracyeonstancy</u> and timer linearity over the range of use; $2.b. - 9. \dots$

Paragraphs A.1 and 6 of this Section for two years. The record shall include the date of the spotcheck; the manufacturer's name, model number, and serial number for both the teletherapy unit and source; the manufacturer's name, model number, and serial number of the instrument used to measure the output of the teletherapy unit; the timer <u>accuracyeonstaney</u> and linearity; the calculated "on-off" error; a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device; the timer <u>accuracyeonstaney</u> and linearity for a typical treatment time; the calculated "on-off" error; the estimated accuracy of each distance-measuring or localization device; the difference between the anticipated output and the measured output; notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, and doors; and the signature of the individual who performed the periodic spot-check.

B. - D.5.e. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2590 (November 2000), LR 30:1183 (June 2004), amended by the Office of Environmental Assessment, LR 31:54 (January 2005), amended by the Office of the Secretary, Legal Affairs Division, LR 32:**.

§763. Training

A. – N. ...

O. Recentness of Training. The training and experience specified in Subsections A-L

of this Section shall have been obtained within the <u>seven</u>five years preceding the date of application, or the individual shall have had continuing applicable experience since the required training and experience was completed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2106 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2590 (November 2000), LR 30:1186 (June 2004), amended by the Office of Environmental Assessment, LR 31:1061 (May 2005), amended by the Office of the Secretary, Legal Affairs Division, LR 32:**.

Chapter 8. Radiation Safety Requirements for Analytical X-Ray Equipment

§804. Area Requirements

A. ...

B. Surveys

1. Radiation surveys, as required by LAC 33:XV.4<u>3</u>20, of all analytical X-ray systems sufficient to show compliance with LAC 33:XV.804.Subsection A- of this Section shall be performed:

B.1.a. - C. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2591 (November 2000), amended by the Office of the Secretary, Legal Affairs Division, LR 32:**.